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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,052	02/21/2002	Sung-Jin Kim	SJKIM-002US	6753

7590

12/02/2002

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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 12/02/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,052

Applicant(s)

KIM, SUNG-JIN

Examiner

Susan Coe

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 16-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed September 23, 2002, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 16-52 have been added.
3. Claims 1-52 are pending.

Election/Restrictions

4. Newly submitted claims 16-52 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 1-15 are related to new claims 16-52 as product and process of use. The two groups of claims are distinct because the product can be used in a different process, such as the use of *Asiasari radix* extracts as antiinflammatories.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-52 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5. Claims 1-15 are examined on the merits.

Specification

6. The amendment filed September 23, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall

Art Unit: 1654

introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendments found in paragraphs 0009, 0010, 0072, 0078, 0083, and 0088 are considered to introduce new matter because these paragraphs now contain material that was not originally found in the specification and does not have support in the original specification. The addition of paragraph 0010 adds new material that was not found originally. In addition, the changes to the experimental protocols in 0072, 0078, 0083, and 0088 represents significant changes to these protocols that does not have original support.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

7. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is indefinite because steps e) and f) both refer to the “solution of step d);” however, the antecedent basis for this is not clear. Specifically, it is not clear if the solution is the chloroform insoluble fraction. If this is the case, it would be more definite if the claim language clearly reflected this.

Claim Rejections - 35 USC § 102

8. Claims 1, 2, and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,889,046 for the reasons set forth on pages 3 and 4 of the previous Office action.

Art Unit: 1654

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the composition of US '046 is not the same as the claimed composition because the composition of US '046 is not disclosed as having the same pharmaceutical effects as those claimed and because US '046 only teaches that the extract contains a single active component. However, US '046 teaches a pharmaceutical composition extracted from *Asiasari radix* that contains numerous derivatives of dioxabicyclo[3.3.0]octane (see bottom of column 3 through top of column 4). Since there can be numerous distinct derivatives, the composition of US '046 is considered to meet applicant's limitation that the extract contain at least two therapeutically effective agents. Since the composition of US '046 is considered to be the same as the claimed composition, the composition of US '046 would inherently have to have the same effects on the body if applicant's invention functions as claimed. For these reasons, the composition taught by US '046 is considered to anticipate the claimed composition.

9. Claims 1, 3-7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Derwent English abstract of Japanese Pat. Appl. No. 05178793 A for the reasons set forth on pages 4 and 5 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the composition of JP '793 is not the same as the claimed composition because the composition of JP '793 is not disclosed as having the same pharmaceutical effects as those claimed and because JP '793 does not teach that the composition contains more than one active component. However, JP '793 teaches a pharmaceutical composition extracted from *Asiasari radix* that contains three different

Art Unit: 1654

monoterpene derivatives. Since there are three active components in the composition of JP '793, their composition is considered to meet applicant's limitation that the extract contain at least two therapeutically effective agents. Since the composition of JP '793 is considered to be the same as the claimed composition, the composition of JP '793 would inherently have to have the same effects on the body if applicant's invention functions as claimed. For these reasons, the composition taught by JP '793 is considered to anticipated the claimed composition.

Claim Rejections - 35 USC § 102/103

10. Claims 1, 3, 4, 6, 7, and 11-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Pat. No. 5,889,046 for the reasons set forth on pages 5 and 6 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that there is no motivation in the reference to arrive at a composition with at least two active ingredients. However, as discussed above, the reference is considered to teach this composition.

In addition, applicant argues that there is no motivation to administer the composition for the claimed ailments. However, claims directed to the method of use are withdrawn from consideration for the reasons stated above.

Claim Rejections - 35 USC § 103

11. Claims 1, 2, 6, 7, and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05178793 A for the reasons set forth on pages 7-9 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that there is no motivation in the reference to arrive at a composition with at least two active ingredients. However, as discussed above, the reference is considered to teach this composition.

In addition, applicant argues that there is no motivation to administer the composition for the claimed ailments. However, claims directed to the method of use are withdrawn from consideration for the reasons stated above.

12. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The

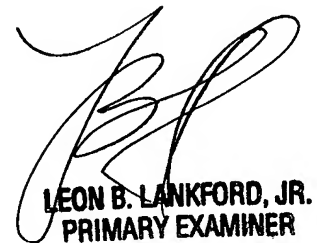
Art Unit: 1654

examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
November 27, 2002



LEON B. LANKFORD, JR.
PRIMARY EXAMINER